K012000

JUL 1 8 2001

510(k) Summary
Bionx Implants Inc.
1.5mm Bone Fixation Kit

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, PA 19422

Contacts: Gerard S. Carlozzi
President and CEO
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5600
Facsimile: 358-3-316 5629

Date prepared: June 15th, 2001

Name of the device:

A.	Trade or Proprietary Name:	1.5mm Bone Fixation Kit
B.	Common Name:	Absorbable Bone Fixation Nail
C.	Classification Name:	Bone Fixation Nail
D.	Device Product Code:	MAI

Predicate Device:

1. Bionx Implants, Inc. SmartNail (K993074)

Intended Use:

Properly used, in the presence of adequate immobilization, 1.5mm Bone Fixation Kit is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

1.5mm Bone Fixation Kit is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) Treatment of physeal fractures in children, because the effect of the implant upon the healing of growth plate has not been tested clinically.

Device Description:

The device description of the 1.5mm Bone Fixation Kit is as follows.

- The implants are composed of poly-L/D-lactide copolymer. This is the very same raw material with SmartNail (K993074)
- Lengths of implants are 16, 18, 20 and 25 mm.
- Diameter of implants is 1.5mm. This is identical with SmartNail (K993074)
- Design of the implant of 1.5mm Bone Fixation Kit is identical with SmartNail (K993074).
- Shelf life is same with SmartNail™.
- Implants and single use, sterile, disposable instruments are packed into blister, which is sealed with the Tyvek® lid. Blister with Tyvek® lid is packed into aluminium foil pouch and sealed.

Substantial Equivalence:

Bionx Implants Inc. 1.5mm Bone Fixation Kit is substantially equivalent to the cleared Bionx Implants Inc. SmartNail (K993074) have the same intended use and principles of operation and very similar technological characteristics.

The instrument set is substantial equivalent with previously cleared Bionx Implants Inc. SmartNail (K993074). Furthermore, the minor technological differences between the Bionx Implants Inc. 1.5mm Bone Fixation Kit and the predicate devices do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2001

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants, Ltd.
P.O. Box 3
FIN-33721 Tampere
Finland

Re: K012000
Trade Name: 1.5mm Bone Fixation Kit
Regulation Number: 888.3030
Regulatory Class: II
Product Codes: HWC and MAI
Dated: June 15, 2001
Received: June 27, 2001

Dear Ms. Annala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K012000

Device Name: **1.5mm Bone Fixation Kit**

Indications for Use:

1.5mm Bone Fixation Kit is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

1.5mm Bone Fixation Kit is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) Treatment of physeal fractures in children, because the effect of 1.5mm Bone Fixation Kit upon the healing of growth plate has not been tested clinically.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012000